

III. In the Claims (Marked Version)

Please amend the claims as follows:

1. (Three Times Amended) A vaccine for the prevention of *Campylobacter* colonization in animals comprising an effective amount of antiserum raised against a flagellaless *Campylobacter* strain wherein the [flagellaless *Campylobacter* strain] antiserum recognizes a 97 kD (+/-5_ kD), a 60 kD (+/-5 kD), and a 13 kD (+/-3 kD) band on a Western Blot.

IV. Remarks

A. Rejections Under 35 USC §112

Reasons rejection is improper:

The law only requires that (1) applicant set forth the invention and (2) the invention is set forth with reasonable definiteness, as would be understood by one of ordinary skill in the art. Here, the term R2 is well-understood in the art.

Argument:

Claim 3 stands rejected under 35 USC §112, 2nd ¶ as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner maintains the position that recitation of the term R2 is not sufficient to enable the invention. Applicants respectfully request reconsideration of the rejection in light of well-established case law and in light of the art cited by the Examiner.

The law is clear. The Federal Circuit has repeatedly explained to the Courts and PTO that the second paragraph of § 112 contains two requirements: first, the claim must

set forth what the applicants regard as their invention, and second, it must do so with sufficient particularity and distinctness, i.e., the claim must be sufficiently definite. *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1377, 55 USPQ2d 1279, 1282 (Fed. Cir. 2000). In determining whether the claim is sufficiently definite, the Courts will and must analyze whether “one skilled in the art would understand the bounds of the claim when read in light of the specification.” *Personalized Media Communications, LLC v. Int’l Trade Comm’n*, 161 F.3d 696, 705, 48 USPQ2d 1880, 1888 (Fed. Cir. 1998). Further, a claim term is sufficiently definite if the term has a reasonably well-understood meaning in the art. *Cf. id.*

Here, the use of the term R2 to describe a flagella-less *Campylobacter* would be well understood in the art. The Examiner contends that Applicants are required to particularly state the differences between *C. jejuni* R2 and other aflagellar strains. However, such a requirement is solely the requirement of the Examiner and not the law. Reference to the article cited by the Examiner by Cathraw et al., titled “Isotype, Specificity, and Kinetics ...”, *Avian Diseases* 38:341-349, at page 344, illustrates that the term R2 is well-known as a descriptor for an a flagellaless strain of *Campylobacter*. Likewise, the article cited by the Examiner by Wassenaar et al., titled “Inactivation of *Campylobacter jejuni* flagellin genes ...”, *The EMBO Journal* 10:8:2055-2061, at page 2055, further illustrates that the term R2 is well-known in the art as a species of a flagellaless *Campylobacter*. Accordingly, the term is distinctly claimed and understood by those of ordinary skill in the art. No further description is required. Therefore, Applicants respectfully request reconsideration of the rejection in light of this response. The term R2 is not an arbitrary label as maintained by the Examiner.

B. Rejections Under 35 USC §102(b)**1. Rejection of Claims 1-2 and 9 by Blaser I*****Reasons the rejection is improper:***

Blaser I does not disclose a vaccine and specifically concludes that the flagellar *C. jejuni* is the only candidate for a vaccine. Applicants have shown, for the first time, that the aflagellate *C. jejuni* is a better candidate as a vaccine.

Argument:

Claim 1-2 and 9 stand rejected under 35 USC §102(b) as being anticipated by an article to Blaser et al. in a journal titled Infection Immunity, Vol. 53(1), July 1986, pp. 47-52 (hereinafter referred to as Blaser I). The Examiner states, from the first office action, that the claimed invention of Claims 1 and 2 are directed to a vaccine composition of antiserum directed to a flagellaless strain of *Campylobacter jejuni*. The Examiner further states that Claim 9 is directed to an antigen protein of *Campylobacter*. However, the Examiner then states that the term vaccine is not being read as a limitation, but rather as an intended use. Applicants previously amended the claims to specify that the claim was directed to a vaccine. Applicants used the phrase "an effective amount" in the body of the claim. Reading the preamble and the body together particularly points out that a vaccine is being claimed.

Claim 1 currently reads as follows:

"A vaccine for the prevention of *Campylobacter* colonization in animals comprising an effective amount of antiserum raised against a flagellaless *Campylobacter* strain."

In the interpretation of the meaning of a preamble, there are several possibilities. First, as the Examiner suggests, a preamble may be interpreted as an intended use. *Rowe v. Dror*, 112 F. 3d 473, 478 (Fed. Cir. 1997). However, a more succinct rule for the interpretation of a preamble is that a preamble has the import that the claims as a whole suggests for it. *Bell Comm. Res., Inc. v. Vitalink Comm., Inc.*, 55 F. 3d 615, 620 (Fed. Cir. 1995). Here, the body of the claim specifically states that an effective amount of antiserum raised against a flagellaless *Campylobacter* strain is claimed. Reading the preamble, a vaccine, with the body clearly indicates that an effective amount of antiserum raised against a flagellaless *Campylobacter* strain is for a vaccine. The Examiner's contention that an effective amount is any amount that is effective to immunoreact with flagellaless *Campylobacter* strain is not tenable when considering the entire claim, i.e., the preamble and the body of the claim together. *See Bell Comm. Res., Inc.*, 55 F. 3d at 620. When taking the import of the whole claim, the preamble does limit the claim to a vaccine.

Moreover, as the Examiner agrees, Applicants specifically claim a flagellaless strain of *Campylobacter*. The Blaser I article specifically concludes that only a flagellar protein, and thus only the strains of flagellar *Campylobacter* that produce flagellar, plays a role in cross protection between strains of different serotype. Therefore, the Blaser I article only discloses that vaccines of the flagellar type work. There is no disclosure of a flagellaless vaccine as claimed by Applicants.

3. Rejection of Claims 1-3 by Cawthraw

Reasons Rejection is Improper:

The rejection is improper because Cawthraw discloses immunization with a flagellar *C. jejuni*. The Cawthraw article specifically states that aflagellate will not function as a vaccine.

Argument:

Claims 1-3 stand rejected under 35 USC §102(b) as being anticipated by an article by Cawthraw et al. in a journal titled Avian Diseases, April-June, 1994, Vol. 38(2) pp. 341-349 (hereinafter referred to as the Cathraw article). It is the position of the Examiner that the Cathraw article discloses anti-*C.jejuni* IgG antibodies induced to a strain of *Campylobacter jejuni*, wherein the antibodies were administered to eggs and ultimately to young chickens. The Examiners position is then that a vaccine of antiserum containing antibodies was passively administered to young chicks in the Cathraw article. Applicants respectfully request reconsideration of the rejection.

The Cathraw article is directed towards vaccines of a flagellar *Campylobacter* strain. In fact, the Cathraw article repeatedly states that a flagella is important to the ability of the *Campylobacter* to act as a vaccine (See p. 347, 2nd ¶, Col. 2; p. 347, 1st ¶, Col. 1; Abstract, last sentence). Accordingly, the Cathraw article does not disclose Applicants' invention. Applicants' invention illustrates that antiserum raised against a *flagellaless* strain of *Campylobacter* is effective as a vaccine. (See Specification, Results, Experiment 1, p. 11, ll. 26-37). Accordingly, and contrary to previous argument, the specification teaches that a flagellar strain of *Campylobacter* does not function as a vaccine, as was commonly thought in the artfield. Therefore, Applicants respectfully request reconsideration.

particularity and distinctness, i.e., the claim must be sufficiently definite. *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1377, 55 USPQ2d 1279, 1282 (Fed. Cir. 2000). In determining whether the claim is sufficiently definite, the Courts will and must analyze whether "one skilled in the art would understand the bounds of the claim when read in light of the specification." *Personalized Media Communications, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 705, 48 USPQ2d 1880, 1888 (Fed. Cir. 1998). Further, a claim term is sufficiently definite if the term has a reasonably well-understood meaning in the art. *Cf. id.* Here, Applicants have claimed a widely used Western Blot. One of ordinary skill in the art would understand such term. Moreover, Applicants specification uses the exact language of the claims. (See page 4, lines 1-9). Accordingly, there is nothing indefinite about the use of the term "recognize."

V. Conclusion

Applicants respectfully request reconsideration of the rejections in light of this response. The application is believed in a condition for allowance and Applicants respectfully request such action. Applicants respectfully request the examiner contact the undersigned attorney for an interview with the Examiner's SPE, Lynette Smith, to expedite prosecution of the case. Please charge deposit account number 02-2334 for any required fees.

Date: 10/22/02

Sincerely,

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The Examiner has directed attention towards page 344 of the article to support the contention that the article discloses passively immunizing young chicks when the antiserum containing antibodies was passively administered to young chicks. The Examiner then directs attention to page 347, first column, last paragraph, the statement "there is evidence of anti-*C. jejuni* IgG antibodies in 1-week-old infected birds, which indicates the presence of maternal antibodies acquired during egg development" (See Cawthraw article, page 347) for support of the contention that the Cawthraw article discloses a vaccine. However, this is anti-*C. jejuni* IgG antibodies to the flagellate strain and not the aflagellate. Therefore, the Examiner's contention is incorrect. Moreover, the remainder of the Cawthraw article discloses the importance of flagellin as an immunogen. (See last paragraph, p. 347). In fact, the Cawthraw article concludes that the presence of circulating maternal antibodies does not confer protection. (See p. 348, left column, 1st ¶). Therefore, the article states that passive immunization was not a vaccine. Applicants respectfully request reconsideration.

4. Rejection under 35 USC §112, 2nd,

Claim 1 stands rejected under 35 USC §112, 2nd ¶, as being indefinite for failing to particularly point out and distinctly claims the subject matter which Applicant regards as the invention. The Examiner contends that one of ordinary skill in the art would not understand, and consider indefinite, the term "recognize a ... band on a Western Blot." Applicants respectfully request reconsideration. As has been aptly pointed out, the law is clear. The Federal Circuit has repeatedly explained to the Courts and PTO that the second paragraph of § 112 contains two requirements: first, the claim must set forth what the applicants regard as their invention, and second, it must do so with sufficient
